IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 6:20-cv-00176

DEFENDANTS' REPLY IN SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Two principles are at the core of this case: First, it matters that consumers understand the particular risks that cigarettes pose—that they are not blindsided by blindness, bladder cancer, or the many other consequences that smokers, and those exposed to cigarette smoke, will suffer. Second, it is constitutional to require cigarette manufacturers to convey those consequences on the packages and advertisements that help bring them about.

Plaintiffs spill a remarkable amount of ink contesting the first principle. In their view, *no* warning can be justified by the goal of informing the public about the risks of a dangerous product—not even one that poses as many, or as serious, risks as cigarettes. But case law and common sense foreclose that position. As even Plaintiffs' cases make clear, the government has a significant interest in providing the public with a range of important information—about public health, campaign finance, or misleading advertisements—without needing to game out how, exactly, the public will use it.

Once the first principle is established, the second follows as a matter of course. The Food and Drug Administration (FDA) selected eleven new cigarette health warnings that provide medically accurate information about the risks of smoking, and the agency marshaled overwhelming evidence that the warnings will improve understanding of those risks. *See* Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15,638 (Mar. 18, 2020) ("the Rule"). It does not offend the First Amendment to require cigarette manufacturers to include these purely factual, uncontroversial warnings on their packaging and advertisements.

In resisting that conclusion, Plaintiffs continue to train most of their fire on quibbles with FDA's process. But if FDA truly had done shoddy work, then Plaintiffs would not devote so much of their brief to selectively plucking quotes from early focus groups or counting cancerous lesions on diseased lungs. FDA undertook years of rigorous research, made careful scientific judgments, and selected warnings that "promote greater public understanding of the risks associated with the use of tobacco products"—the very aim that Congress singled out in the Tobacco Control Act (TCA). 15 U.S.C. § 1333(d)[2]. The warnings are constitutional; FDA's rulemaking complies with the Administrative Procedure Act (APA); and Defendants, accordingly, are entitled to summary judgment.

ARGUMENT

I. THE RULE IS CONSISTENT WITH THE FIRST AMENDMENT.

The Rule is consistent with the First Amendment at any level of scrutiny. But because the Rule requires only the disclosure of purely factual and uncontroversial information, "the less exacting scrutiny described in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985)," applies. *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249 (2010). Before turning to the application of *Zauderer*, however, Defendants address Plaintiffs' suggestion that the FDA is owed no deference for factual findings within its area of expertise.

A. FDA is entitled to deference on scientific matters within its expertise.

Plaintiffs ask this Court to ignore the "high level of deference" that courts afford FDA's "scientific analysis of the evidence before it[.]" *Pharm. Mfg. Research Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020) (citation omitted). Plaintiffs insist that such deference has no place in the context of a First Amendment claim because—as Defendants noted in their opening brief—courts must "make an independent assessment of a citizen's claim of constitutional right when reviewing agency decision-making." *Tex. Office of Pub. Util. Counsel v. FCC*, 183 F.3d 393, 410 (5th Cir. 1999) (citation omitted); *see also* Pls.' Opp'n Br. 3, ECF No. 59; Defs.' Br. 16, ECF No. 37. But Plaintiffs contort an uncontroversial proposition—that this Court reviews *de novo* whether the Rule complies with the First Amendment—into an unrecognizable one, suggesting that this Court should ignore FDA's substantial expertise just because Plaintiffs bring constitutional claims.

The Supreme Court rejected that false equivalence in *Trump v. Hawaii*, holding that although courts "of course 'do not defer to the Government's reading of the First Amendment,' the Executive's evaluation of the underlying facts is entitled to appropriate weight[.]" 138 S. Ct. 2392, 2422 (2018) (citation omitted). Although the *Hawaii* Court noted that deference to Executive-Branch fact-finding is "particularly" warranted in cases "involving 'sensitive and weighty interests of national security and foreign affairs,'" 138 S. Ct. at 2422 (citation omitted), deference is *also* appropriate when the "agency's particular technical expertise is involved," *Medina Cty. Envtl. Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010).

Porter v. Califano is not to the contrary. *See* 592 F.2d 770 (5th Cir. 1979). There, the Fifth Circuit simply held that it was "wrong[]" for a district court to "defer[] to [an] agency determination of [a plaintiff's] constitutional rights." *Id.* at 781. In reaching that conclusion, the court emphasized the same distinction outlined above—*i.e.*, courts generally defer "to agency fact-finding" because of "agency expertise in a particular specialized or technical area," but agencies do not get deference on questions of First Amendment law because "courts, not agencies, are expert on the First Amendment." *Id.* at 780 n.15. Here, the question is not whether FDA gets deference for its conclusion that the warnings are constitutional (it does not); rather, the question is whether FDA gets deference for its evaluation of scientific evidence (it does). Plaintiffs do not dispute that the only court of appeals to have considered *that* issue held that FDA should receive its usual deference. *See R.J. Reynolds Tobacco Co. v. FDA* ("*R.J. Reynolds I*"), 696 F.3d 1205, 1217-18 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst. v. USDA* ("*AMI*"), 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc).

B. *Zauderer* governs the First Amendment analysis.

1. *Zauderer* is not limited to disclosures that correct deceptive speech.

a. Plaintiffs argue for heightened First Amendment scrutiny on the theory that *Zauderer* "applies only in the context of preventing deception of consumers." Pls.' Opp'n Br. 5. But they do not dispute that *every* court of appeals to have considered the issue has rejected that limit. *See* Defs.' Br. 18-19. And they do not engage with the reasoning of those cases or of *Zauderer* itself. Plaintiffs ignore, for instance, that *Zauderer* directly distinguished "between disclosure requirements and outright prohibitions on speech[.]" 471 U.S. at 650; *see also id.* at 651 (noting that "appellant's constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal"). And they similarly fail to address *AMI*, in which the *en banc* D.C. Circuit considered *Zauderer* (as well as the Supreme Court's application of *Zauderer* in *Milavetz*) and determined that the Court's reasoning "sweeps far more broadly than the interest in remedying deception." 760 F.3d at 22; *see also, e.g.*, *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113-14 (2d Cir. 2001).

Plaintiffs continue to elevate language from *Zauderer* that was "simply descriptive of the circumstances to which the Court applied its new rule." *AMI*, 760 F.3d at 22; *see also* Defs.' Br. 18-20. But Plaintiffs do not contend that *any* of their cases actually held that *Zauderer* applies only to disclosures that correct deceptive speech.[1] Nor do they explain how their position squares with the Supreme Court's refusal to "question the legality of health and safety warnings long considered permissible." *Nat'l Inst. of Family & Life Advocates v. Becerra* ("*NIFLA*"), 138 S. Ct. 2361, 2376 (2018). Instead, Plaintiffs assert that "many such disclosures can be justified by reference to consumer deception," Pls.' Opp'n Br. 7, but are silent as to how that can be so. What "deception" (in Plaintiffs' telling) do nutrition facts or lists of adverse drug reactions correct? More to the point, Plaintiffs fail to explain why a government purpose of correcting deception should unlock a lower tier of First Amendment scrutiny. A requirement that drug manufacturers disclose a list of dangerous adverse reactions is no more a burden on speech than a requirement that debt-relief agencies inform customers that their services might include filing for bankruptcy. *See Milavetz*, 559 U.S. at 232-33, 251 (upholding the latter under *Zauderer*). There is no sound basis for applying different levels of scrutiny to subsets of purely factual, uncontroversial commercial disclosures. This Court should adopt the "unanimous[]" conclusion that *Zauderer* "applies even in circumstances where the disclosure does not protect against deceptive speech." *CTIA - The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 843 (9th Cir. 2019).

b. Even if *Zauderer* were limited only to disclosures that address consumer deception, the Rule should still be sustained. The Rule was "intended in part to correct consumer misperceptions regarding the risks presented by cigarettes, and thereby 'to dissipate the possibility of consumer confusion or deception.'" 85 Fed. Reg. at 15,645 (quoting *Zauderer*, 471 U.S. at 651). As the Sixth Circuit found, the TCA's requirement for pictorial health warnings is indeed "reasonably related to

[1] Plaintiffs do suggest that *Allstate Insurance Co. v. Abbott*, 495 F.3d 151 (5th Cir. 2007), involved a disclosure requirement, rather than a restriction on speech. *See* Pls.' Opp'n Br. 6. But the Fifth Circuit plainly saw the Texas law at issue in *Allstate* as a restriction: It described the law as "[p]rohibiting Allstate from giving an exclusive recommendation" to body repair shops that it owned. *Allstate*, 495 F.3d at 165. The court, accordingly, analyzed that prohibition under *Central Hudson*, with only a brief mention of *Zauderer*. *See id.* at 166 & n.59.

preventing consumer deception" in light of clear evidence "that most people do not understand the full dangers of tobacco use." *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 563, 565 (6th Cir. 2012). Instead of addressing that authority, Plaintiffs invent a series of hurdles for the government to clear before a disclosure counts as addressing deception.[2] But they cite no cases actually holding that such hurdles exist. *See* Pls.' Opp'n Br. 8. And they do not dispute the key point: that cigarette health warnings are necessary in part because the tobacco industry (including some of these Plaintiffs) lied for decades about the health effects of smoking, while getting millions of Americans addicted to a product that causes myriad life-ruining consequences. *See* Defs.' Br. 20; *see also* Amicus Br. for the States at 10-17, ECF No. 47.

2. The warnings are purely factual and uncontroversial.

The warnings convey "facts [that] are directly informative of intrinsic characteristics of [a] product" and are not "so one-sided or incomplete that they would not qualify as 'factual and uncontroversial[.]'" *AMI*, 760 F.3d at 27. The warnings should therefore be evaluated under *Zauderer*. *See* 471 U.S. at 651. Plaintiffs broadly assert three reasons why the warnings do not count as "factual and uncontroversial." Each is unavailing.

First, Plaintiffs' attempt to question the accuracy of the text of the warnings is baseless. Pls.' Opp'n Br. 15. Tellingly, they do not identify any warning statement that is inaccurate. Doing so would be a tall order, given that the Surgeon General has determined—at the "highest level" of evidence of causal inference—that smoking cigarettes causes each of the health conditions identified in the warnings. *See* 85 Fed. Reg. at 15,670. Instead, Plaintiffs quibble with FDA's selection of health conditions and its choice of causal language. *See* Pls.' Opp'n Br. 15. But they ignore that, if those

[2] The lines Plaintiffs draw are curious. For instance, they suggest that the particular "commercial speech at issue" must itself be misleading in order for *Zauderer* to apply, *see* Pls.' Opp'n Br. 7 (emphasis omitted)—a result that would limit the government's ability to require companies to correct past deceptive statements. And they suggest that a manufacturer's misrepresentations must pertain to the specific "subject matter of the[] warnings," *id.* at 8—a requirement that would insulate manufacturers who make broad claims about health from having to make disclosures about more specific health consequences. *See, e.g.*, AR 03966-67 (describing how tobacco advertising used "[k]ey words such as 'light,' 'smooth,' and 'mild,' . . . to convey health-related messages" and later relied on "imagery of active, healthy models" for a "more subtle" message).

criticisms had merit, they would also doom the existing warnings. *See* Defs.' Br. 28. For instance, one of the current Surgeon General's warnings reads: "Smoking *Causes* Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy." Pub. L. No. 98-474, § 4, 98 Stat. 2200, 2202 (1984) (emphasis added). Yet despite Plaintiffs' professed concern about "the[] use of the word 'cause'" in FDA's *new* warnings, Pls.' Opp'n Br. 15, they repeatedly endorse the Surgeon General's warnings. *See* Compl. ¶ 1 ("For nearly fifty-five years, cigarette packages have included textual warnings that convey factual, uncontroversial information about the risks of smoking."); *see also* Pls.' Br. 1, ECF No. 34.

The Rule's warnings use the same causal language as the Surgeon General's reports, which include assessments of "the strength of the evidence establishing that smoking cause[s] a specific disease." AR 38076;[3] *see also, e.g.*, AR 38748 ("[S]moking causes diabetes."). That Plaintiffs nonetheless insist that the warnings' text is inaccurate reveals how far they are willing to venture in order to avoid *Zauderer*, including their familiar tactic of muddying settled scientific waters.

Second, Plaintiffs claim that the images that FDA paired with the text statements are non-factual and controversial. They start by doubling down on their claim that *no* images can count as "purely factual and uncontroversial" under *Zauderer*. *See* Pls.' Opp'n Br. 8-9. But they have yet to cite a single case that stands for that sweeping proposition, *see id.*; Pls.' Br. 8,[4] and *Zauderer* forecloses it. There, as Defendants have explained, the Court rejected an argument that images inherently "create[] unacceptable risks that the public will be misled, manipulated, or confused." *Zauderer*, 471 U.S. at 648; *see also id.* at 649 (finding the particular image at issue to be "accurate and nondeceptive"). Plaintiffs' only response is that *Zauderer* endorsed the use of images in advertisements, rather than disclosures. *See* Pls.' Opp'n Br. 8 n.6. But that distinction is irrelevant in assessing Plaintiffs' blanket claim that consumer-facing images are necessarily misleading. Plaintiffs do not (and could not reasonably) suggest that an image is more misleading if it happens to be selected by the government, rather than

[3] U.S. Department of Health and Human Services, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General* (2014).

[4] To the extent Plaintiffs would claim that *R.J. Reynolds I* is such a case, the court was clear that it was the specific images FDA chose—like a "man wearing a T-shirt emblazoned with the words 'I QUIT'"—that it found concerning, not the concept of images, writ large. *See* 696 F.3d at 1216.

an advertiser. Plaintiffs' concession that the use of images "in advertisements is not always misleading" therefore dooms their contention that images are always off-limits in disclosures. *Id.*

Plaintiffs' categorical skepticism of images suffers from two additional flaws. First, they decline to explain how the standard they invent for assessing warnings—that the government must "make a record-based showing" that a warning "conveys solely an unambiguous, factually correct meaning," Pls.' Opp'n Br. 8—can be squared with their endorsement of the current Surgeon General's warnings, which use subjective adverbs like "greatly" and "serious." *See* Defs.' Br. 28. Second, they offer no reason to believe that a warning with both text *and* a concordant image is likely to result in misinterpretation. *See* Defs.' Br. 28. Indeed, Plaintiffs do not acknowledge, much less contest, FDA's determination that the "evidence shows that larger cigarette health warnings containing text paired with images are more effective than text-only warnings at increasing knowledge and public understanding" of smoking's health effects. 85 Fed. Reg. at 15,664 (citing more than a dozen sources).

Instead, Plaintiffs mischaracterize the record by suggesting that FDA's third qualitative study supports a finding that the text-image pairings are confusing. *See* Pls.' Opp'n Br. 9. Even on its own terms, this criticism fails. Consider the first example Plaintiffs point to, of a participant who was shown an earlier version of the warning for erectile dysfunction. That participant indicated "the picture is still confusing," AR 26157, which Plaintiffs cite to suggest that the participant was "confused and misled," *see* Pls.' Opp'n Br. 9. But the transcript tells a different story. When asked if seeing "the picture *together* with the" warning's text helped the participant "understand the picture," his answer was "Yeah, it does[.]" AR 26157 (emphasis added). He then noted that "the picture is still confusing," but the confusion was apparently about the woman's positioning on the bed, not the meaning of the warning. *See id.* ("Because the girl, she's facing a different way in a bed, and so it's like, what direction is the bed actually facing?"). In other words, the text-image pair *promoted* understanding, and the participant showed no signs of misunderstanding the bottom-line message.[5]

[5] Even though the feedback about the bed has no bearing on whether the erectile dysfunction warning is misleading, FDA still took that feedback to heart. *Compare* AR 23643 (version of the warning used in the third qualitative study), *with* AR 39778 (version of the warning used subsequently in the second quantitative study, which makes clear that the man and woman are on the same bed).

Stepping back, this example helps illustrate why it is a mistake to talk about images in a vacuum, divorced from the warnings' text. *See* Defs.' Br. 28. But it is also a microcosm of the selective, misleading criticism of FDA's studies that pervades Plaintiffs' briefs. *See e.g.*, Defs.' Br. 39-41. Plaintiffs repeatedly stumble into a "pitfall with qualitative studies" by placing "too much emphasis on a single quote or comment that sparks interest." 85 Fed. Reg. at 15,666 (citation omitted). In the above example, the comment they emphasize happens to reinforce Defendants' position. But even if that had not been the case, cherry-picked observations from focus groups cannot transform accurate warnings into ones that are "so one-sided or incomplete" that they no longer count as "factual and uncontroversial[.]" *AMI*, 760 F.3d at 27. That is particularly true given that Plaintiffs often dwell on focus-group excerpts while ignoring the results of FDA's large empirical studies. Curated quotes suggesting that warnings are "confusing" may make for interesting reading, but they do not outweigh the results of FDA's second quantitative study, which found (among other things) that all eleven final warnings outperformed the current Surgeon General's warnings on perceived informativeness, perceived understandability, and perceived helpfulness in understanding health effects. 85 Fed. Reg. at 15,658. Plaintiffs claim the warnings leave consumers confused; the data indicate the opposite.

Plaintiffs' remaining argument about the accuracy of FDA's warnings is that they are "exaggerated and subject to misinterpretation." Pls.' Opp'n Br. 13. As explained below, in Defendants' opening brief, and the Rule itself, Plaintiffs are wrong. But even if their criticisms of certain individual warnings were taken at face value, that would not render the warnings "controversial." Instead, Plaintiffs have at most suggested that the warnings are imperfect or lack nuance that Plaintiffs would prefer. Take, for instance, Plaintiffs' criticism of the image for the warning that "Tobacco smoke causes fatal lung disease in nonsmokers." Plaintiffs initially claimed that the lungs in the image "do not look like a non-smoker's lungs." Pls.' Br. 26 (citation omitted). But after Defendants pointed out that FDA had thoroughly debunked that charge in the Rule, *see* 85 Fed. Reg. at 15,673, Plaintiffs dropped the issue. *See* Defs.' Br. 29-30; Pls.' Opp'n Br. 13. Plaintiffs' only remaining criticism of the image comes from a single doctor, who opined that three cancerous

lesions appearing on the lungs of a non-smoker is "uncommon" but "not unheard of." AR 28121 (cited at Pls.' Opp'n Br. 13).

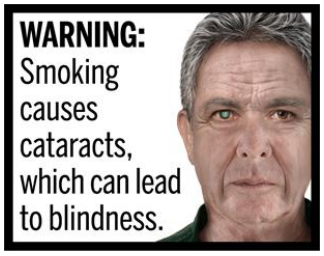
This is the kind of nitpicking on which Plaintiffs rely to avoid *Zauderer*—a claim that FDA's depiction of the cancer that Plaintiffs' products indisputably cause in non-smokers is *accurate*, but may (in the opinion of one doctor) be off by a lesion or two from the modal presentation of the disease. *But see* 85 Fed. Reg. at 15,673 (confirming the accuracy of the depiction of "the cancerous lesions and discoloration"). Similarly, Plaintiffs criticize the warning depicting amputated toes on the ground that "multiple toes that were amputated *at the same time*" would be "uncommon" for the most prevalent form of peripheral arterial disease. Pls.' Opp'n Br. 13 (emphasis added). "At the same time" is a key qualifier, because Plaintiffs do not dispute that, "[f]or those with particularly severe artery blockages caused by peripheral arterial disease, an astounding 25% have amputations *each year*." Defs.' Br. 30 (citing 85 Fed. Reg. at 15,681). In other words, the flaw in FDA's image (in Plaintiffs' telling) is not that too many toes are missing, but rather that it is insufficiently clear that smoking is more likely to result in *serial* amputations, instead of *simultaneous* ones. Plaintiffs fail to explain why that distinction—even if it were accurate—is sufficient to change the level of First Amendment scrutiny.

Nor do Plaintiffs establish why their other criticisms of the warnings' accuracy render *Zauderer* inapplicable. Those criticisms fall into two categories: that the warnings do not adequately convey the relative prevalence of a condition or treatment (harm to children, cataracts, fetal growth, heart disease, bladder cancer, erectile dysfunction, diabetes); and that the warnings depict a condition for which people might receive earlier treatment (head and neck cancer, cataracts). *See* Pls.' Opp'n Br. 13-15.

As to the first category, a warning is not "controversial" for addressing a serious—even if comparatively infrequent—consequence of smoking. *See, e.g.*, 21 C.F.R. § 201.57(c)(6) (requiring prescription drug labels to describe "clinically significant adverse reactions," including ones that "are serious even if infrequent"). Nor is a warning "controversial" if it does not include information about the specific likelihood of a given risk or medical intervention. Again, Plaintiffs consider the current Surgeon General's warnings "uncontroversial," Compl. ¶ 1, even though they do not mention the "absolute or relative risk," Pls.' Opp'n Br. 15, of the conditions they address, *see* Pub. L. No. 98-474,

§ 4, 98 Stat. at 2202. Warnings that provide important, accurate information are not "controversial" just because there is more that could be said on the topic. *See CTIA*, 928 F.3d at 847 (upholding a required disclosure about cell phone radiation that "provides in summary form information that . . . consumers should know in order to ensure their safety"). Such a requirement would be particularly unworkable for cigarette warnings, given how many serious health consequences result from smoking and how much scientists are still learning about of the harms that cigarettes cause. *See* AR 38026 explaining that "new causal conclusions are still being added to th[e] long list" of "health consequences and diseases caused by tobacco use"). No single warning can fully portray smoking's harms.

Finally, Plaintiffs' explanation for why the warnings for head and neck cancer and for cataracts are "controversial" is particularly galling. *See* Pls.' Opp'n Br. 13-14. Plaintiffs do not dispute that cigarettes cause tumors and cataracts that look like this:



Yet Plaintiffs maintain that it is misleading to accurately depict these consequences of smoking because many people—indeed, all "reasonable" people, according to Plaintiffs, Pls.' Br. 27—would treat these conditions before the consequences fully manifest. That is absurd. A warning about the risk of obesity is not misleading because it fails to mention the availability of stomach stapling. Moreover, as Plaintiffs implicitly acknowledge, many Americans who do not have access to, or cannot afford, adequate medical care *will* develop tumors and cataracts that look like the ones above. *See* 85 Fed. Reg. at 15,674, 15,684. When that happens, poverty or "lack of transportation" will not be the cause of their disfigurement, *see* Pls.' Opp'n Br. 13; Plaintiffs' products will.

Third, the possibility that some consumers may have an emotional reaction to the warnings does not make them inaccurate or controversial. In arguing to the contrary, Plaintiffs continue to rely on claims about FDA's intent. *See, e.g.*, Pls.' Opp'n Br. 10 (discussing the "purpose of the graphics"); *id.* at 11 ("intended to shock"); *id.* at 12 ("evidence of [the government's] intentions"). But FDA's

intent is clear: It seeks only to "promote greater public understanding of the negative health consequences of cigarette smoking," 85 Fed. Reg. at 15,639, not to scare consumers or "browbeat [them] into quitting," *R.J. Reynolds I*, 696 F.3d at 1217. That was true throughout FDA's iterative process for developing the warnings: It chose warning statements that promote understanding, *see* Proposed Rule, 84 Fed. Reg. 42,754, 42,769 (Aug. 16, 2019); it chose images that "present[] the effects of smoking in a clear and objective format" and "feature health effects of smoking without being overly menacing or grotesque," AR 23399; its studies sought to measure understanding and did not attempt "to investigate the effect of the[] warnings on . . . emotional reactions," AR 50772;[6] and it rejected comments that sought to make the warnings "more 'gross' or 'shocking,'" 85 Fed. Reg. at 15,670. Finally, FDA affirmed in the Federal Register that each warning "does not contain any elements intended to evoke a negative emotional response." *See* 85 Fed. Reg. at 15,672-84.

Despite the overwhelming evidence that FDA meant what it said, Plaintiffs insist something else was afoot. They try to put Defendants into a double-bind: If the text warnings are purely factual, but FDA nonetheless chose to add images to the warnings, then surely (Plaintiffs' flawed syllogism concludes) "the graphics are doing something *other* than conveying factual information." Pls.' Opp'n Br. 9. Not so. Plaintiffs ignore the consensus across the communications-science literature that "messages that are accompanied by images closely linked to the message content (*i.e.*, concordant) are shown to increase the likelihood that consumers will comprehend the message." 84 Fed. Reg. at 42,764; *see also, e.g.*, AR 8494[7] ("Graphic warning labels improve smokers' recall of warning and health risks[.]"); AR 10326[8] ("The findings demonstrate that pictorial health warning labels that depict the risk of specific health effects from smoking can increase beliefs and knowledge about the negative

[6] Plaintiffs claim it was "inexcusable" not to study the emotional impact of the warnings. Pls.' Opp'n Br. 11 n.9. But they provide no reason why FDA should have studied an outcome it was not trying to achieve.

[7] Andrew A. Strasser, et al., *Graphic Warning Labels in Cigarette Advertisements: Recall and Viewing Patterns*, 43(1) Am. J. Prev. Med., 41-47 (2012).

[8] Jessica L. Reid, et al., *Influence of Health Warnings on Beliefs about the Health Effects of Cigarette Smoking, in the Context of an Experimental Study in Four Asian Countries*, 14 Int'l J. Envt. Res. Public Health 2017, 868 (2017).

health consequences of smoking, particularly for health effects that are lesser-known."). In other words, images in health warnings can *reinforce* the factual information conveyed by the text.

Next, Plaintiffs point to examples of individual reactions to the warnings as evidence that FDA must have been trying "to convey the government's ideological message[.]" Pls.' Opp'n Br. 10. This, of course, gets the causal arrow backwards. As Defendants have explained, and Plaintiffs have not disputed, the fact that "some may find truthful depictions of the harms caused by cigarettes upsetting is perhaps unsurprising, but the level of First Amendment scrutiny does not somehow *increase* when warnings concern products that happen to cause more profound harms." Defs.' Br. 3. Plaintiffs decline to engage with any of the cases Defendants cited on this point, *see id.* at 32, which make clear that "provok[ing] a visceral response" does not bring a health warning "outside *Zauderer*'s ambit." *Disc. Tobacco*, 674 F.3d at 569; *see also CTIA*, 928 F.3d at 847 (upholding required disclosure about cell-phone radiation that "may not be reassuring, but . . . is hardly inflammatory").

Finally, Plaintiffs reiterate their slippery-slope fear of "untenable results." Pls.' Opp'n Br. 11. But Plaintiffs' hypotheticals are red herrings. *See* Defs.' Br. 32 n.18. Plaintiffs point to no other product for which (1) the health risks are of the same magnitude as cigarettes, (2) the government has spent decades determining how best to inform consumers of those risks, (3) existing warnings are demonstrably ineffective, and (4) the government has implemented a multi-year, multi-study strategy for developing accurate warnings that promote understanding of health risks.

Ultimately, Plaintiffs' attempts to paint the warnings as non-factual and controversial fall short because they rest on a caricature of FDA's efforts. The agency was not careless with its causal statements, sloppy with its depiction of health conditions, or two-faced in carrying out its research. Rather, an agency with deep expertise in public health and the regulation of consumer products painstakingly developed accurate warnings that promote understanding of the negative health consequences of smoking. Those warnings should be assessed (and upheld) under *Zauderer*.

C. The Rule should be upheld under *Zauderer*.

1. The government has a legitimate interest in promoting understanding of the negative health consequences of smoking.

a. Plaintiffs stand by their remarkable position that the government has no valid interest in helping ensure that consumers understand the health consequences of the most dangerous consumer product on the market. Instead, Plaintiffs insist, the government must "show that its approach is effective at achieving a legitimate real-world objective such as 'encourag[ing] smokers to quit.'" Pls.' Opp'n Br. 16. But the acrobatics required to hold that line collapse within the span of a page of Plaintiffs' brief. In attempting to distinguish the cases Defendants cite, Plaintiffs posit that the cases "discuss *either* an interest in preventing consumer deception *or* an interest in affecting real-world behavior[.]" *Id.* at 17 (emphasis added). In other words, in Plaintiffs' own telling, the government can, in fact, have a valid interest in preventing deception *without* linking that interest to changes in "real-world behavior." That is Defendants' point: The government can require the disclosure of information that allows the public to make informed choices about important issues without reaching any conclusion about the particular choices the public will ultimately make. *See* Defs.' Br. 23-24.

The language Plaintiffs quote from *Citizens United v. Federal Election Commission*, 558 U.S. 310 (2010), helpfully illustrates the point. There, the Court explained that a required disclosure "permit[ted] citizens and shareholders to react to the speech of corporate entities in a proper way." 558 U.S. 310, 371 (2010). But the Court did not determine *how* citizens and shareholders would react; it simply highlighted their improved ability to do so. The same is true here: these warnings give consumers better information about the risks of smoking, and *consumers* then decide whether to take up smoking, to try to quit smoking, or to change where or when they smoke.[9]

[9] Plaintiffs maintain that there is no valid "'barometer' for assessing the . . . effectiveness" of this sort of disclosure requirement. Pls.' Opp'n Br. 16. But FDA's careful study of the degree to which its warnings will promote understanding of the negative health consequences of smoking is exactly that. Assessing the extent to which the warnings correct an important knowledge gap on the part of consumers is not "defin[ing] 'effectiveness' however [the agency] sees fit." *R.J. Reynolds I*, 696 F.3d at 1221. Rather, it is judging the agency by the particular problem it has chosen to solve, which is the same approach courts regularly take in deciding whether to uphold a disclosure requirement.

To be sure, there must be value to the disclosed information—*i.e.*, "the interest at stake must be more than the satisfaction of mere 'consumer curiosity.'" *CTIA*, 928 F.3d at 844 (citation omitted). But understanding that cigarette smoking can lead to blindness or bladder cancer is not a matter of idle "curiosity"; it is knowledge of material risks to one's health. One of the cases Plaintiffs cite, *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996), illustrates this distinction. There, the court preliminarily enjoined a state law requiring dairy manufacturers to disclose whether their cows had been treated with a growth hormone, and it rejected the argument that "consumer interest alone was sufficient to justify requiring" a warning. *Id.* at 73. But the key piece of the court's reasoning was that the warning would have been for "a production method that has no discernable impact"; indeed, "the FDA ha[d] 'concluded that . . . there are no human safety or health concerns associated with food products derived from cows treated'" with the hormone. *Id.* at 69, 73. If, however, there had been "some indication that th[e] information bears on a reasonable *concern* for human health or safety," manufacturers could have been "compelled to disclose it." *Id.* at 74 (emphasis added). Then-Judge Kavanaugh drew the same distinction in *AMI*, suggesting that requirements for "nutrition labels and health warnings"—including "health warnings on cigarette packages"—plainly further a substantial interest, whereas disclosures that serve "consumer interest alone" do not. *AMI*, 760 F.3d at 31-32 (Kavanaugh, J., concurring in the judgment) (quoting *Int'l Dairy Food*, 92 F.3d at 74).

The government's interest in FDA's warnings is not some blanket interest in providing miscellaneous information. It may be "academic," Pls.' Opp'n Br. 21, to understand that meat comes from a particular country, *see AMI*, 760 F.3d at 31 (Kavanaugh, J., concurring in the judgment), or from hormone-treated cows, *Int'l Dairy Food*, 92 F.3d at 69. But no one can seriously dispute that understanding that smoking may harm your children, clog your arteries, and cost you your toes is material information. *See Pub. Citizen Inc. v. La. Att'y Disciplinary Bd.*, 632 F.3d 212, 219 (5th Cir. 2011) ("[P]eople will perceive their own best interests if only they are well enough informed[.]").

b. Plaintiffs' fallback position—that there is no need for *any* further information about the health consequences of smoking, *see* Pls.' Opp'n Br. 18-21—is baseless. As an initial matter, this is yet another example of Plaintiffs adopting a position that is foreclosed by their endorsement of the current

Surgeon General's warnings. *See* Compl. ¶ 1. If the public is already omniscient about the risks of smoking, then why are *any* cigarette health warnings necessary?

More to the point, there is strong evidence that the public lacks sufficient understanding about the risks of cigarettes. That shortcoming exists even for some of the most common health consequences of smoking. *See* Defs.' Br. 24; *see also* 85 Fed. Reg. at 15,655 (noting that the "lack of data from youth" in the data reviewed by Plaintiffs' expert, Professor Klick, may "bias the results as younger people may be less informed about the range of health consequences caused by smoking"). But as relevant here, Plaintiffs do not meaningfully dispute that the public lacks information about the specific health conditions the warnings address. *Compare* Defs.' Br. 24-25, *with* Pls.' Opp'n Br. 19-20.[10]

Instead, Plaintiffs' argument is, in essence, that the government should be indifferent as to whether smokers have actual knowledge of the risks they expose themselves (and others) to by smoking. *See* Pls.' Opp'n Br. 20-21. That nihilism represents a fundamental departure from the value typically placed on public-health disclosures. *See* Defs.' Br. 21-26. Plaintiffs point to no other context in which the government would consciously decline to require the disclosure of common, life-altering consequences on the theory that the only thing people need to know is whether something is "very or extremely harmful to [one's] health." AR 27908 n.46[11] (cited at Pls.' Opp'n Br. 20). Imagine consulting with a surgeon about the risks of surgery and being told: "all I'm obligated to let you know is that, on a scale of 'mild,' to 'extremely harmful,' the potential complications from this surgery are 'extremely harmful.'" Or imagine picking up a prescription at a pharmacy and, instead of a list of significant adverse reactions, seeing only a note that the "known side effects are moderate."

Common sense dictates that more detailed information can matter when making consequential decisions about one's health. And that intuition is confirmed, in the specific context of cigarette health

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[10] As Plaintiffs all but admit, their reliance on PATH data to measure "knowledge *related* to"—instead of knowledge *directly about*—a subset of the risks addressed in the warnings is unavailing. Pls.' Opp'n Br. 19-20 & n.16 (emphasis added). For instance, the PATH survey items addressed broader, or more commonly known, health conditions than those addressed in the warnings—*e.g.*, "harm to fetuses," instead of the more specific "stunt[ing] fetal growth." 85 Fed. Reg. at 15,655.

[11] Statement of Jonathan Klick, Ph.D., J.D. (attached as Exhibit C to RAI Services comment).

warnings, by congressional findings, *see, e.g.*, Pub. L. No. 98-474, § 2 (purpose of making "Americans more aware of *any* adverse health effects of smoking" and "enabl[ing] individuals to make informed decisions about smoking" (emphasis added)), and court decisions, *see, e.g.*, *United States v. Philip Morris USA Inc.*, 566 F. 3d 1095, 1123 (D.C. Cir. 2009) ("[R]easonable purchasers of cigarettes would consider these statements important."); *Disc. Tobacco*, 674 F.3d at 567 ("What matters . . . is not how many consumers ultimately choose to buy tobacco products, but that . . . consumers possess accurate, factual information when deciding whether to buy tobacco products.").

Plaintiffs, accordingly, have it exactly wrong when they claim that Defendants' position is that government can rely on any "informational interest" without having "to do *anything* to show that the information is actually important." Pls.' Opp'n Br. 21. Rather, Defendants have shown that all three branches have endorsed the importance of promoting greater understanding of the risks of smoking.

2. The Rule reasonably furthers the government's interest.

There is a straight line between the interest in promoting greater understanding of the negative health consequences of smoking and the warnings FDA selected in the Rule. Indeed, FDA chose those warnings precisely because its second quantitative study demonstrated that the warnings directly further FDA's goal. Plaintiffs' arguments for setting aside those findings remain unpersuasive.

First, Plaintiffs fail to engage with Defendants' arguments refuting the alleged "methodological problems" with the study. Pls.' Opp'n Br. 22. They do not dispute that "a nationally representative sample" is not necessary "to demonstrate a valid and reliable effect." 85 Fed. Reg. at 15,663; *see also* AR 54055 (Peer Review Report) (finding that FDA's "study population" was "appropriate to address the research questions"). And they ignore entirely the defense of FDA's choice of "new information" and "self-reported learning" as the key metrics for predicting which warnings would promote greater understanding of the health consequences of smoking. *Compare* Defs.' Br. 35-37, *with* Pls.' Opp'n Br. 22. In other words, although Defendants are certainly entitled to deference for FDA's methodological choices, *see Kennecott Greens Creek Min. Co. v. Mine Safety & Health Admin.*, 476 F.3d 946, 956 (D.C. Cir.

2007), the strength of the agency's analysis stands on its own. *See also, e.g.*, AR 54070 (Peer Review Report) ("Both [quantitative] studies are very well done in terms of design and data analysis.").

Second, using the current Surgeon General's warnings as the control condition was a sensible choice, as the Peer Review Report confirms. *See id.* (explaining that "the current standards for warnings" were "an appropriate control group[]"). FDA's aim was to assess whether the existing warnings should be replaced with new ones for the sake of increasing understanding about the negative health consequences of smoking; measuring the degree to which the new warnings do (or do not) outperform the existing ones was a sensible way to make that determination.

Third, having ignored Defendants' explanation why "new information" and "self-reported learning" were appropriate metrics, Plaintiffs nonetheless insist that FDA was obligated to select warnings that performed well on the "health beliefs" measure. *See* Pls' Opp'n Br. 23-24. But they do not contest FDA's key findings about health beliefs: First, nine of the eleven final warnings outperformed the Surgeon General's warnings on the "health beliefs" measure between Sessions 1 and 2 of the study (two days later), 85 Fed. Reg. at 15,659; second, six of eleven warnings outperformed the Surgeon General's warnings on that measure between Sessions 1 and 3 of the study (17 days later), *id.*; and third, health beliefs are unlikely to change "after only brief exposure to a warning." *Id.* at 15,662. Plaintiffs suggest these results were poor, but they neither explain why nor indicate what FDA should have expected instead. They cite no evidence that health beliefs should change faster or that the effects of limited exposure to warnings should linger longer.

Finally, the fact that the warnings performed well across a range of measures forecloses Plaintiffs' repeated argument that it is unclear whether study participants actually learned anything of relevance from the warnings. *See* Pls.' Opp'n Br. 18 n.12, 21, 23. For starters, the "new information" metric was not the open-ended inquiry that Plaintiffs suggest. *See id.* at 18 n.2. Rather, FDA asked a focused question: "Before today, had you heard about the specific smoking-related health effect *described* in the warning?" AR 39707 (emphasis added). It is reasonably clear, then, that a participant who answered "no" had learned about the specific health condition addressed in the warning.

Moreover, the warnings' strong marks on perceived understandability, *see* 85 Fed. Reg. at 15,659, reinforce that participants did not have difficulty understanding the warnings' messages.

3. The Rule is no broader than reasonably necessary.

The Rule is not "unjustified or unduly burdensome," *Zauderer*, 471 U.S. at 651, because it is "no broader than reasonably necessary," *NIFLA*, 138 S. Ct. at 2377. Plaintiffs do not contest any of the case law Defendants cited about the leeway the government has in identifying a "'reasonable fit' between means and ends," *AMI*, 760 F.3d at 26-27. *See* Defs.' Br. 41. Plaintiffs nonetheless treat *Zauderer* as akin to a least-restrictive-means test, arguing that FDA was required to "test" alternatives before adopting the Rule. *See* Pls.' Opp'n Br. 24-25. But *Zauderer* rejected that approach, emphasizing that courts should not "strike down [disclosure] requirements merely because other possible means by which the State might achieve its purposes can be hypothesized." 471 U.S. at 651 n.14.[12]

In any event, FDA *did* consider—and rejected—the suggestion that it rely solely on public-information campaigns, explaining that such campaigns "do not reach every person who looks at a package of cigarettes or advertisements[.]" 85 Fed. Reg. at 15,648. Plaintiffs suggest that FDA has no business worrying about whether its warnings reach every smoker or would-be smoker. *See* Pls.' Opp'n Br. 25. But as FDA explained in the Rule, for more than 50 years Congress has chosen to place warnings on cigarette packages and advertisements; confining these new warnings to a narrower audience would therefore not serve as an adequate alternative. *See id.*

The remaining alternatives Plaintiffs propose are similarly wanting. Plaintiffs incorrectly state that "FDA does not explain why [textual warnings] could not work well again." Pls.' Opp'n Br. 26.

[12] Plaintiffs claim that the availability of an alternative was "fatal to the government's position in *NIFLA*," Pls.' Opp'n Br. 24-25, but the portion of the case they cite does not apply here. In *NIFLA*, the Court considered two disclosure requirements: one for licensed clinics, and another for unlicensed ones. *See* 138 S. Ct. at 2368. Because the disclosure requirement for licensed clinics did not "relate[] to the services that licensed clinics provide," the Court held that "*Zauderer* ha[d] no application" to *that* disclosure requirement. *Id.* at 2372; *see also id.* at 2377 (assuming, without deciding, that *Zauderer* applied to the disclosure requirement for *unlicensed* clinics). Yet it was only in the Court's discussion of the licensed clinics—*i.e.*, the portion of the opinion *not* governed by *Zauderer*—that the Court emphasized that California could have tried "a public-information campaign." *Id.* at 2376.

In fact, FDA discussed this at length in both the proposed and final rules. 84 Fed. Reg. at 42,762-65; 85 Fed. Reg. at 15,648. Plaintiffs offer no response to FDA's conclusion that the scientific literature strongly "supports that pictorial cigarette warnings promote greater public understanding about the health consequences of smoking" as compared to text-only warnings.[13] 85 Fed. Reg. at 15,648.

Finally, Plaintiffs offer no meaningful response to the evidence FDA marshaled in support of the size and placement of the warnings. *See* Defs.' Br. 43. They simply assert that the evidence would *also* justify even larger warnings. Pls.' Opp'n Br. 26. But like the Sixth Circuit in *Discount Tobacco*, 674 F.3d at 565, FDA reasonably concluded that leaving 50% of cigarette packages and 80% of cigarette advertisements for tobacco manufacturers' branding was sufficient, *see* 85 Fed. Reg. at 15,647—a result that likely would not hold for warnings that take up 90% of a package. And although Plaintiffs highlight cases where other warning labels were struck down, those cases are distinguishable. *See Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (invalidating a label requirement under strict scrutiny, not *Zauderer*, because the required label sticker "communicates a subjective and highly controversial message"); *Am. Beverage Ass'n v. City & Cty. of San Francisco*, 916 F.3d 749, 757 (9th Cir. 2019) (en banc) (distinguishing the warning at issue from larger "tobacco and prescription warnings"). By contrast, in the only case to have considered the speech implications of the size and location of the TCA's cigarette warnings, the warnings were upheld. *See Disc. Tobacco*, 674 F.3d at 565.

D. The warnings survive any heightened scrutiny.

For the foregoing reasons, the Rule should be upheld under *Zauderer*. But it also withstands heightened scrutiny. Plaintiffs ignore every argument in Defendants' opening brief as to why the intermediate scrutiny of *Central Hudson* is the highest form of scrutiny that could apply. *See* Defs.' Br. 45-46. When a "challenged provision[] regulate[s] only commercial speech," the choice is between *Zauderer* and *Central Hudson*; strict scrutiny is not an option. *Milavetz*, 559 U.S. at 249.

[13] Plaintiffs' principal source of evidence on the viability of textual warnings is the analysis of Dr. Iyengar. *See* Pls.' Opp'n Br. 26. But FDA carefully explained in the Rule why that study is unreliable, including that it is missing details about how the study was conducted, lacks information on sample recruitment, lacks detail about the control condition, and lacks clarity on whether "survey items were drawn from previously validated or previously used surveys." 85 Fed. Reg. at 15,668.

The Rule is constitutional under *Central Hudson*. It furthers the government's substantial interest in informing consumers about the negative health consequences of smoking. Although Plaintiffs persist in trying to draw a line between "informational" and "real-world" interests, *see* Pls.' Opp'n Br. 27, the cases they cite render that distinction untenable. *See supra* at 13-14. In particular, the interests they highlight from *Citizens United*—"avoiding confusion" and "enabling citizens to react to the speech of corporate entities," Pls.' Opp'n Br. 27 (citation and alteration omitted)—are just as "informational" as the interest FDA pursued through the Rule. In both cases, the government chose to require the disclosure of information that can have a substantial effect on people's lives—whether by enabling them to hold corporations to account or by arming them with knowledge about one of the most consequential choices they may make for their personal health.

Additionally, the Rule directly advances the government's interest by providing consumers with important health information, as FDA's extensive quantitative research demonstrates. *See supra* at 16-18. Finally, FDA's careful consideration of alternatives to the warnings demonstrates that the Rule reflects "a 'reasonable fit' between means and ends." *AMI*, 760 F.3d at 26-27; *see also supra* at 18-19. The Rule, accordingly, satisfies heightened scrutiny.

II. THE TCA'S REQUIREMENTS FOR PICTORIAL HEALTH WARNINGS ARE CONSTITUTIONAL.

Plaintiffs have not come close to meeting their burden "to establish that 'no set of circumstances exists under which [the TCA] would be valid' . . . or that the statute lacks any 'plainly legitimate sweep.'" *United States v. Stevens*, 559 U.S. 460, 472 (2010) (citation omitted). Instead, they imply—citing no authority—that an agency gets just "two shots at crafting a constitutional rule" before the underlying statute is struck down. Pls.' Opp'n Br. 29. Such a result is inconsistent with the high bar for facial challenges, and it is particularly ill-suited to the TCA provisions at issue here. As the Sixth Circuit made clear, the TCA "simply requires 'color graphics depicting the negative health consequences of smoking.'" *Disc. Tobacco*, 674 F.3d at 569 (quoting 15 U.S.C. § 1333(d)[1]). Plaintiffs have provided no persuasive reason to think that *all* such warnings must necessarily run afoul of the First Amendment, even under their cribbed reading of *Zauderer* and its progeny.

III. FDA COMPLIED FULLY WITH THE APA IN PROMULGATING THE RULE.

A. The Rule is not arbitrary and capricious.

As FDA's thorough process for developing the warnings shows, the agency "examined the relevant data and articulated a satisfactory explanation" for its action, "including a rational connection between the facts found and the choice made." *U.S. Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (citation omitted). Accordingly, the Rule easily survives deferential APA review.

Plaintiffs' APA claim principally criticizes the agency's cost-benefit analysis. But Plaintiffs do not dispute that the TCA requires *no* cost-benefit analysis, that FDA performed the analysis pursuant to Executive Orders that preclude judicial review, or that "FDA did not invoke its cost-benefit analysis as a reason for the Rule." Defs.' Br. 50. Accordingly, even if there had been "flaws in that analysis," they did not "infect the Rule" and thus provide no basis to challenge it. Pls.' Opp'n Br. 30 n.24.

In any event, the agency's cost-benefit analysis was sound. Plaintiffs assert that it "was quintessentially arbitrary and capricious" not to monetarily quantify the Rule's benefits, Pls.' Opp'n Br. 30, but that contention ignores Defendants' opening brief, the explanation for the cost-benefit analysis in the Final Regulatory Impact Analysis, and the decision in *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 406-07 (D.D.C. 2017), *aff'd on other grounds*, 944 F.3d 267 (D.C. Cir. 2019), which upheld a similar "break-even" approach in an FDA cost-benefit analysis.

Next, Plaintiffs argue that FDA was obliged under the APA to "consider whether the Rule would reduce smoking." Pls.' Opp'n Br. 30. Plaintiffs rely on the D.C. Circuit's recent decision in *Cigar Association of America v. FDA*, 964 F.3d 56 (D.C. Cir. 2020), where the D.C. Circuit interpreted a provision of the TCA that requires FDA to consider the likelihood that certain regulations will affect tobacco use. *See* 21 U.S.C. § 387f(d)(1). In interpreting that provision—as applied to FDA warnings for cigars and pipe tobacco—the D.C. Circuit observed that there was a need to consider "whether the warnings will actually affect product usage." *Cigar Ass'n*, 964 F.3d at 62. But the D.C. Circuit interpreted § 387f(d)(1) because that was the provision FDA invoked in issuing the cigar and pipe tobacco warnings; by contrast, a different provision of the TCA governs the issuance of pictorial health warnings for cigarettes, *see* 15 U.S.C. § 1333(d)[1]. Unlike for warnings issued under

§ 387f(d)(1), Congress chose *not* to make the issuance of pictorial health warnings contingent on findings about tobacco use; instead, it focused FDA's attention on whether the warnings will "promote greater public understanding of the risks associated with the use of tobacco products." 15 U.S.C. § 1333(d)[2]. FDA made *that* finding, but it did not have any obligation to make a separate finding about tobacco usage that Congress expressly chose not to require in this context.

Finally, Plaintiffs point to two alleged failures in the notice-and-comment process. First, they claim that FDA failed to respond to criticism of its qualitative studies. That is wrong. FDA explained the role the studies played in its iterative process, acknowledged that it used the studies to help "test and refine" the warning statements and images, and explained that further reliance on them would have been inappropriate in light of the small sample and lack of generalizable data. 85 Fed. Reg. at 15,666; *see also* Defs.' Br. 11-12. Second, Plaintiffs allege that FDA did not adequately address the peer review report. But the only specific point that Plaintiffs claim went unaddressed is the selection of measures for FDA's quantitative studies, *see* Pls.' Br. 52—an issue Defendants have addressed at length. *See* Defs.' Br. 36 & n.23 (highlighting support in the literature and from peer reviewers).[14]

B. FDA complied with the APA's requirements for notice-and-comment rulemaking.

When conducting notice-and-comment rulemaking, "the agency must issue a '[g]eneral notice of proposed rule making'" and "must 'give interested persons an opportunity to participate.'" *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) (quoting 5 U.S.C. § 553). Although Plaintiffs submitted extensive comments, they claim that their "opportunity to comment" was insufficiently "meaningful," Pls.' Opp'n Br. 31, because (1) they were not (yet) in possession of *all* of FDA's raw study data (just detailed reports about the studies); and (2) a *supplementary* comment period was too short. Both arguments fail. And even if either had merit, any error was harmless.

[14] Although Plaintiffs suggest that the public should have been able to comment on the report, they tellingly do not include that argument in their discussion of FDA's alleged notice-and-comment failures. *See* Pls.' Opp'n Br. 31-35. Had they done so, the argument would fail for many of the same reasons as Plaintiffs' claims about the study data. *See infra* Section III.B.1.

1. FDA had no obligation to publish all of the raw data from all of its studies with its "general notice of proposed rulemaking."

Defendants cited several Fifth Circuit cases rejecting Plaintiffs' raw-data theory, which confirm that "the public 'need not have an opportunity to comment on every bit of information influencing an agency's decision.'" *Tex. Office of Pub. Util. Counsel v. FCC*, 265 F.3d 313, 325-27 (5th Cir. 2001) (quoting *Texas v. Lyng*, 868 F.2d 795, 799 (5th Cir. 1989)). Plaintiffs' responses are unpersuasive.

Chemical Manufacturers Association v. EPA, for example, rejected a nearly identical argument: that the EPA had violated notice-and-comment requirements by "relying on economic data . . . that were never made available to the public for comment." 870 F.2d 177, 200 (5th Cir.), *clarified on other grounds on reh'g*, 885 F.2d 253 (5th Cir. 1989). The Fifth Circuit found that there was no error because the EPA "adequately advised interested parties of the method [it] had followed, the financial data it proposed to rely on, and its intention to develop an economic-impact study"—even though it "did not reveal the new . . . data" during the comment period. *Id.* at 201-02. Plaintiffs argue that the EPA in *Chemical Manufacturers* "updated and expanded its data source in response to industry criticism," Pls.' Opp'n Br. 33, which they presumably intend as a contrast to FDA's actions here. But the relevant point is that the Fifth Circuit was not troubled by an agency's "relying on economic data . . . that were never made available to the public for comment." *Chem. Mfrs. Ass'n*, 870 F.2d at 200. And that was because in that case—just like this one—the agency had "adequately advised interested parties of the method the [agency] had followed" through other means. *Id.* at 201-02. Plaintiffs do not dispute that they received—and commented extensively on—hundreds of pages of detailed reports summarizing and discussing the very data that is now the subject of their raw-data argument.[15]

None of this precedent should be surprising: as Defendants explained, Defs.' Br. 51, 54, the APA requires only a "*[g]eneral* notice of proposed rule making," including "either the terms or *substance*

[15] As for *Corrosion Proof Fittings* and *Aqua Slide*, Plaintiffs may be right that neither "reached a holding," Pls.' Opp'n Br. 33 n.29, on the notice-and-comment question, because the regulation at issue was struck down on other grounds not relevant here. Defendants never suggested otherwise. *See* Defs.' Br. 55. But it is telling that Plaintiffs' only response to these two additional Fifth Circuit opinions criticizing their position is a holding-vs.-dicta quibble.

of the proposed rule or a *description* of the *subjects and issues*." 5 U.S.C. § 553(b) (emphases added). Plaintiffs' interpretation would raise a new judge-made hurdle that exceeds "the maximum procedural requirements" imposed by the text of the APA, *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978). Plaintiffs offer no response to this argument.[16]

2. There was sufficient time for comments on the qualitative study reports.

Plaintiffs continue to argue that the 15-day *supplemental* comment period—offered after the original 60-day comment period, and after FDA published its qualitative study reports—was too short. Plaintiffs seem to believe that a 15-day comment period (or perhaps anything shorter than 60 days) is *per se* unlawful. But in some circumstances, 15 days is more than enough. *See, e.g.*, *Omnipoint Corp. v. FCC*, 78 F.3d 620, 629-30 (D.C. Cir. 1996) (rejecting a challenge to a 7-day comment period, among other reasons because interested parties already had some pre-existing knowledge about the issues at stake in the rulemaking) (internal quotations and citation omitted). This is one of those circumstances, given the narrow scope of the new comment period; the original opportunity to comment that had already been provided; and Plaintiffs' extensive, pre-existing familiarity with the issues. *See Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 534 (D.C. Cir. 1982) (upholding 30-day comment period where the agency had been engaged "with members of the industry for over five years").

Plaintiffs rely on cases addressing the length of an agency's *primary* comment period, *see* Pls.' Br. 55, but continue to overlook that the *supplemental* comment period was opened solely because of the new qualitative study reports—that is, *four new documents*. *See* 84 Fed. Reg. 60,966, 60,967-68 (Nov. 12, 2019) (reopening comment period "to allow comment on the additional materials"). Because the

[16] Plaintiffs try to make hay of an FDA memorandum that noted that publishing raw study data could allow third parties to analyze it in potentially "selective, biased, or misleading ways," Pls.' Opp'n Br. 33; *see* AR 23863.1 (citing literature cautioning against deviating from a preselected statistical analysis plan, to guard against data dredging). But that is irrelevant—what matters is whether FDA satisfied its notice-and-comment obligations. Here, it did. In any case, Plaintiffs ignore all the other portions of the same memorandum that undermine their position. *See, e.g.*, AR 23863.1 ("[T]he raw data are not necessary for replicating the studies or evaluating the adequacy or scientific rigor of FDA's consumer research."); AR 23863.2 ("Because the themes and feedback from the qualitative studies were comprehensively summarized in the study reports, the verbatim transcripts are not needed to meaningfully comment on the adequacy or scientific rigor of the qualitative studies.").

scope of the materials at issue in the 15-day supplementary comment period was but a miniscule fraction of those at issue during the original 60-day comment period, Plaintiffs' cases are inapposite.

3. Any notice-and-comment error was harmless.

Even if the agency had erred, procedural missteps under the APA that do not cause "substantial prejudice" must be excused. *Chem. Mfrs. Ass'n*, 870 F.2d at 202; 5 U.S.C. § 706. That burden falls on Plaintiffs. *See, e.g.*, *Tex. Office*, 265 F.3d at 326-27. They have failed to meet it.

a. Raw Study Data. On the question of whether Plaintiffs suffered "substantial prejudice" from lack of earlier access to raw study data, notably, Plaintiffs do not respond *at all* to any of the Fifth Circuit precedent cited by Defendants rejecting very similar claims. *See Chem. Mfrs. Ass'n*, 870 F.2d at 202 ("[W]e fail to discern any substantial prejudice from the EPA's use of the 1981-86 Dun & Bradstreet data to supplement the other information on which it relied. We therefore decline to overturn the regulations[.]"); *Texas v. Lyng*, 868 F.2d 795, 800 (5th Cir. 1989) ("[F]ailure to allow public comment after the issuance of the task force report was harmless."). In their opening brief, Defendants also noted that independent peer reviewers "found the absence of the raw study data to be no obstacle to meaningful analysis and commentary on FDA's studies." Defs.' Br. 59. Plaintiffs now pluck a few out-of-context quotations, Pls.' Opp'n Br. 35, in which some reviewers asked about *other types* of information—as peer reviewers do. But *none* asked for the raw study data that Plaintiffs are now concerned with. Again, Plaintiffs had access to *all of the same information* as the reviewers. If these experts had enough information to offer detailed analyses of FDA's studies, so did Plaintiffs.

Even setting all of that aside, the administrative record produced in this litigation included all of the raw study data. Predictably, none of it was material—as confirmed by Plaintiffs' decision to include *none of it* in their brief. Instead, they simply assert without explanation that the data they buried in an appendix somehow shows "that the warnings are confusing, misleading, and designed to provoke negative emotional reactions." Pls.' Opp'n Br. 34. That appendix includes only quotes from the *qualitative* studies, and even if the Court were to accept Plaintiffs' invitation to hunt through it—despite

it being *Plaintiffs*' burden to show prejudice—the excerpts will offer nothing material that readers of the study *reports* were not already aware of. That, after all, was the purpose of the reports.

b. Length of Additional Comment Period. Nor can Plaintiffs demonstrate "substantial prejudice" based on the length of the supplemental comment period. Most obviously, that is because Plaintiffs (and others) actually *did* submit extensive comments during that period. *See Fla. Power & Light Co. v. United States*, 846 F.2d 765, 772 (D.C. Cir. 1988) (finding "no evidence that petitioners were harmed by the short comment period," where the agency received extensive comments anyway). And although Plaintiffs now speculate about various things they wish they said or did, *see* Pls.' Opp'n Br. 33-34, they never persuasively explain why those things could not have been accomplished within 15 days. For example, it beggars belief that Plaintiffs—with or without the assistance of their able counsel—needed more than 15 days to compile the material they ultimately "collated into an appendix." *See id.* The document is 8 pages long. *See* ECF No. 34-4. And that is all even *accepting* the (unsupported and implausible) premise that cherry-picked quotations from early focus groups would have made a persuasive case to disregard the results of empirical research with 9,760 participants. *See PDK Labs. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand.").

IV. THE RULE IS AUTHORIZED BY THE TOBACCO CONTROL ACT.

Plaintiffs' curious interpretations of the TCA—(1) "that FDA can adjust the text of the warning statements only *after* promulgating a graphic warnings rule," Pls.' Opp'n Br. 35, and (2) that the number of warnings is fixed at nine—both still fail for the lack of any basis in the statute's text.

1. Defendants previously explained that Plaintiffs' primary statutory-authorization argument "is entirely atextual" because "no statutory provision . . . requires FDA to first issue warnings with the Act's default statements, and then wait 15 months or more" before trying to revise the warning statements. Defs.' Br. 64. Plaintiffs have still failed to locate the missing text that they need, responding only that "this argument . . . is rooted squarely in the statute's use of 'accompany' in Section 201(a), as well as the inclusion of the term 'color graphics' in Section 202(b)." Pls.' Opp'n Br. 35.

Neither answer checks out. As for the word "accompany," there is no timing or sequencing requirement to be found in the general requirement that the FDA "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)." 15 U.S.C. § 1333(d)[1]. That language is not about modifying the warning text, let alone about *when* modifications are permitted. And as for the phrase "color graphics," Plaintiffs rely on the following sentence: FDA "may adjust the format, type size, color graphics, and text of any of the label requirements." 15 U.S.C. § 1333(d)[2]. Although that language is at least about *modifying* the statements, it still says nothing about *when* FDA may do so. *See* Defs.' Br. 65.

2. Plaintiffs' second statutory argument is that the TCA "does not authorize FDA to change the number of warnings." Pls.' Opp'n Br. 36. For this argument, Plaintiffs do not even *try* to identify any relevant statutory text, and instead claim only that "it is up to *Defendants* to identify statutory language that allows FDA to change the number of warnings[.]" Pls.' Opp'n Br. 36 (emphasis added). But Defendants already did: with certain exceptions not relevant here, "Section 202(b) authorizes FDA to change 'any of the label requirements,' 15 U.S.C. § 1333(d)[2]"—including their number. Defs.' Br. 65. Once again, Plaintiffs offer no meaningful response.

Defendants also pointed to the TCA's preemption provision: "[e]xcept to the extent the Secretary requires *additional or different* statements on any cigarette package by a regulation, . . . no statement relating to smoking and health, other than the statement required by [the statute], shall be required on any cigarette package." 15 U.S.C. § 1334(a)) (emphasis added). Congress's expectation that FDA might not only require "different" statements, but also "*additional*" ones, is quite hard to reconcile with Plaintiffs' nine-is-the-magic-number theory.[17]

3. Even if Plaintiffs' reading of the statute were the better one, that would not be enough. Instead, because FDA's interpretation is at least reasonable, Defendants would still prevail under

[17] Plaintiffs hypothesize that the "additional or different" statements at issue might only include tar and nicotine yield disclosures authorized by 15 U.S.C. § 1333(e). *See* Pls.' Opp'n Br. 36. But that theory likewise has no basis in statutory text. In fact, Congress did not even require such disclosures, making it especially unlikely that that narrow category was Congress's only concern in drafting the TCA's preemption provision.

Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842-44 (1984). Plaintiffs offer no argument in response, other than the bold assertion that "FDA's approach is unambiguously foreclosed by the statute's text." Pls.' Opp'n Br. 36. But as explained above, there is not only no text that *forecloses* Defendants' reading, there is no text that *supports* Plaintiffs' reading.

V. PLAINTIFFS' REQUESTS FOR RELIEF ARE OVERBROAD.

A. Any unlawful portions of the Rule should be severed.

Although the Rule is lawful in its entirety, if the Court disagrees, Congress specified the path forward: if the Rule, or "any application of" the Rule "to any . . . circumstance is held to be invalid, the remainder of" the Rule, "and the application of" the Rule "to any other . . . circumstance shall not be affected and shall continue to be enforced to the fullest extent possible." 21 U.S.C. § 387 (note). In other words, Congress has *required* severability, and to the greatest possible extent. As Defendants have explained, Defs.' Br. 67-70, that congressional command would be dispositive of any severability questions that arise here—even before considering FDA's intent, or its separate severability findings.

1. Plaintiffs do not dispute that Congress may require regulatory severability, or that such a congressional command must be respected. Instead, Plaintiffs argue that a *separate* provision of the Tobacco Control Act somehow trumps its explicit severability clause. Plaintiffs hang their hat entirely on the following sentence: "[T]he Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)." 15 U.S.C. § 1333(d)[1]. The use of the word "accompany," according to Plaintiffs, means that "Congress has expressly decided that a graphic warnings rule must involve both graphics and text, so those two portions of the Rule cannot be severed from each other." Pls.' Opp'n Br. 37.

This argument fails. As Plaintiffs acknowledge, it is "a fundamental rule of statutory interpretation" that "specific provisions trump general provisions." *Navarro-Miranda v. Ashcroft*, 330 F.3d 672, 676 (5th Cir. 2003) (cited in Pls.' Opp'n Br. 37). But on a question of *severability*, the TCA's *severability clause* is necessarily the more specific command. If a severability analysis is necessary, Congress provided specific instructions: "the remainder of" the Rule, "and the application of" the

Rule "to any other . . . circumstance shall not be affected and shall continue to be enforced to the fullest extent possible." 21 U.S.C. § 387 (note). The word "accompany" does not change that result.[18]

2. If the Court were to accept Plaintiffs' invitation to ignore Congress's severability instructions, it would then have to consider (1) "the intent of the agency" and (2) "whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broads. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001). As for FDA's intent, Plaintiffs seem to no longer dispute that, "in a circumstance where some but not all of the rule's provisions are invalidated, FDA's intent is for the other provisions to go into effect." 85 Fed. Reg. at 15,695.

As to whether portions of "the regulation could function sensibly" on their own, *Broads. Ass'n*, 236 F.3d at 22, "FDA has considered each provision independently and concluded that the individual portions of this rule are workable on their own." 85 Fed. Reg. at 15,695. Plaintiffs seem not to dispute that "[t]hat conclusion is entitled to deference." Defs.' Br. 69. And it is more than reasonable, given FDA's conclusions that *each* warning "demonstrate[s] statistically significant improvements" over the current Surgeon General's warnings with respect to the key metrics. 85 Fed. Reg. at 15,658. Plaintiffs do assert that it would not be "sensible" for "the erectile dysfunction warning," Pls.' Opp'n Br. 38, for example, to survive alone. And, to be sure, both Congress and the FDA intended that *all* of the warnings take effect. But it is hard to imagine any basis on which all of the warnings would be invalidated except one, and Plaintiffs do not even hypothesize such a theory.[19]

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[18] Plaintiffs attach significance to their suggestion that the Rule's requirements are, as Plaintiffs argue, "part of the same provision," although they fail to specify what they mean by "provision." Pls.' Opp'n Br. 37. In fact, the Rule's key requirements are in separate, easily dissectible sub-parts. *See, e.g.*, Section 1141.10(a)(1) (requiring "[o]ne of the following textual warning label statements"); Section 1141.10(a)(2) (requiring "[a] color graphic to accompany the textual warning label statement"); Section 1141.10(c)(2) (cigarette pack "top 50 percent" requirement).

[19] Plaintiffs note correctly that the D.C. Circuit in *R.J. Reynolds I* vacated FDA's previous warning requirements in their entirety, *see* 696 F.3d at 1222, but the issue of severability was not raised in the Government's briefs, and the D.C. Circuit never discussed it.

B. Nationwide relief is inappropriate.

Plaintiffs ignore Defendants' argument that the Tobacco Control Act answers the nationwide-injunction question for purposes of this case: Congress specified that, even if "the application of any [] provision" of the TCA, or regulations issued pursuant to the TCA, "to *any person* or circumstance is held to be invalid, the remainder of" the TCA or the relevant regulations "and the application of such provisions to *any other person* or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible." 21 U.S.C. § 387 (note) (emphases added). The text speaks for itself and, apparently, Plaintiffs have no response.[20]

Plaintiffs also brush off Defendants' concern that, on Plaintiffs' theory, "should FDA prevail in the *Philip Morris* case"—a nearly identical case proceeding in the District of Columbia—"ordering nationwide relief here would effectively deprive the United States of the benefit of that victory." Defs.' Br. 72. Plaintiffs are correct that some courts have ignored similar concerns, and have "enter[ed] nationwide injunctions" even "in cases that are being litigated in multiple fora," Pls.' Opp'n Br. 39, as the Government is well aware, *see Hawaii*, 138 S. Ct. at 2424-25 (Thomas, J., concurring)). Respectfully, those courts have misinterpreted Article III and traditional principles of equity, and have paid insufficient attention to the problems created by this ahistorical practice, especially in litigation against the United States. *See Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring) ("[T]he routine issuance of universal injunctions is patently unworkable."). This Court need not and should not follow suit.

CONCLUSION

For the foregoing reasons, together with the reasons in Defendants' opening brief, the Court should grant Defendants' cross-motion for summary judgment, deny Plaintiffs' motion for summary judgment, and deny—as moot or on the merits—Plaintiffs' motion for a preliminary injunction.

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[20] This language from the TCA—more specific, and more recent than the APA's authorization to "set aside" unlawful "agency action"—also disposes of Plaintiffs' suggestion that "vacatur" is generally the "standard remedy for an unlawful regulation" in a challenge to agency action. Pls.' Opp'n Br. 38. Plaintiffs' assertion is question-begging (vacatur as to whom?), *see* Defs.' Br. 72-73, but the Court need not address it here, given the plain language of the TCA and Plaintiffs' failure to respond.

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